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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,879	08/12/2002	Pieter Cornelis Langeveld	246152016800	1306

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EXAMINER

ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 01/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,879

Applicant(s)

LANGEVELD ET AL.

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8,11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6-4-2004</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on 6-29-04 is acknowledged.

Claims 1-6, 8 and 11-12 are pending. Claims 8 and 11 have been withdrawn from consideration as being drawn to non-elected inventions. Claims 1-6 and 12 are currently under examination.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 and 12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 and 14-16 of copending Application No. 10/089,874. Although the conflicting claims are not identical, they are not patentably distinct from each other because the aforementioned application is directed to a process for determining the presence or absence of an antimicrobial

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residue in a sample. The claimed process differs only in that it is directed to a process for determining the presence or absence of an antimicrobial residue in a food sample, i.e., any food sample, of which egg samples are a subset. Also, the copending application recites that any natural disturbing compound is inactivated in the contacted sample and in the test (claim 1, step (ii)), while the instant application recites that the contacted sample and test are heated for a sufficient time to inactivate any natural inhibiting compound in the sample (claim 1, step (ii)).

These steps are identical.

Claims 1, 2, 5, 6, 7, 14 and 15 of the copending application read on claims 1-6 of the instant application. Claim 6 of the copending application recites the components of the test. Claim 12 of the instant application recites an example of a natural inhibiting compound broadly claimed in the copending application. Although these claim limitations are not recited in the claims of the copending application, they are part of its disclosure as a preferred embodiment of the invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

As discussed above, claims 1-8 and 14-16 are directed to an invention not patentably distinct from claims 1-6 and 12 of commonly assigned Application No. 10/089879.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned Application No. 10/089874, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to

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resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 12 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 12 are rendered vague and indefinite by the use of the term “any natural inhibiting compound”, because it cannot be determined whether or not an inhibiting compound is a compound that disturbs the action of the antibiotic, i.e., an antibiotic inhibitor, or a compound that inhibits the growth of the test organism, (i.e., a growth inhibitor), or a compound that inhibits the reading of a test result from the sample. The specification discloses two examples of natural disturbing compounds, blood pigments and lysozyme, but does not indicate in what way these compounds disturb the test.

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Claim 1 is further rendered vague and indefinite by the use of the term “test suitable for determining the presence or absence of an antimicrobial residue...”. It is unclear whether said “test” is a product or a method.

Claim 6 is rendered vague and indefinite by the use of the term “indicators”. It is unclear what is encompassed by said term. What process or product is associated with said “indicators”?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Charm et al. (U.S. Patent 5,354,663). Charm discloses a test method for the determination of antimicrobial drugs in food samples, in which the test method includes placing a sample into a container and heating the sample to a temperature sufficiently high to destroy the natural inhibitors in the sample. The method further comprises adding a test to the sample and incubating the mixture containing the sample and the test to determine whether or not microbial growth occurs (see column 3, line 27, to column 4, line 10, in particular, column 3, lines 32-35). Thus, Charm et al. anticipate the limitations of the instant claims.

Claims 1-6 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Inglis et al. (Journal Assoc. Off. Anal. Chem. Vol. 61, No.5, 1978, pages 1098-1102 – IDS).

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Inglis et al. disclose an assay procedure for detecting antimicrobial residues (streptomycin) in egg samples wherein said samples and test organism (spores) are heated to 85 degrees for 15 minutes and subsequently added to agar plates for determine whether spore growth was inhibited. Inhibition of said growth is indicative of the presence of an antimicrobial residue (see Method section on pages 1098-1099). Moreover, Inglis et al. specifically disclose that the heating step was to inactivate lysozyme activity (natural inhibiting compound)[see abstract].

Claims 1-6 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Katz et al. (Journal Assoc. Off. Anal. Chem. Vol. 61, No.5, 1978, pages 1103-1106 – IDS).

Katz Inglis et al. disclose an assay procedure for detecting antimicrobial residues (neomycin) in egg samples wherein said samples and test organism (spores) are heated to 85 degrees for 15 minutes and subsequently added to agar plates for determine whether spore growth was inhibited. Inhibition of said growth is indicative of the presence of an antimicrobial residue (see Method section on pages 1103-1104). Moreover, Katz et al. specifically disclose that the heating step was to inactivate lysozyme activity (natural inhibiting compound)[see abstract].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charm et al. (U.S. Patent 5,354,663).

Charm discloses a test method for the determination of antimicrobial drugs in food samples, in which the test method includes placing a sample into a container and heating the sample to a temperature sufficiently high to destroy the natural inhibitors in the sample. The method further comprises adding a test to the sample and incubating the mixture containing the sample and the test to determine whether or not microbial growth occurs (see column 3, line 27, to column 4, line 10, in particular, column 3, lines 32-35). Charm et al. differs from the instant invention in that they do not explicitly disclose the temperature range and duration of heating with regard to samples comprising eggs. However, since Charm et al. disclose that samples need to be heated to a temperature sufficiently high to destroy the natural inhibitors in the sample, the claimed temperature ranges and durations constitute an optimization of the disclosed method. The skilled artisan would necessarily adjust the temperature and heating duration for a given sample type.

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Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert A. Zeman
January 11, 2005


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